



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0473]

Human Immunodeficiency Virus Patient-Focused Drug Development and Human Immunodeficiency Virus Cure Research: Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and an opportunity for public comment on human immunodeficiency virus (HIV) Patient-Focused Drug Development and HIV Cure Research. Patient-Focused Drug Development is part of FDA's performance commitments in the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). FDA is interested in obtaining patient input on the impact of HIV on daily life, available therapies to treat the condition, and patients' views on issues related to HIV cure research, such as perceived benefits and acceptable risks for participating in HIV cure research and clear communication of benefits and risks through informed consent.

DATES: The public meeting will be held on Friday, June 14, 2013, from 9:30 a.m. to 5:30 p.m. Registration to attend the meeting must be received by Wednesday, June 5, 2013. Submit electronic or written comments by July 14, 2013. See the SUPPLEMENTARY INFORMATION section for information on how to register for the meeting.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, in section A of the Great Room (room 1503), Silver Spring, MD 20993. Entrance for the public meeting participants is through Building 1, where

routine security check procedures will be performed. For parking and security information, please refer to

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Submit electronic comments to www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the complete agenda and additional meeting background material approximately 5 days before the meeting at:

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm348598.htm>

FOR FURTHER INFORMATION CONTACT: Pujita Vaidya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1199, Silver Spring, MD 20993, 301-796-0684, FAX: 301-847-8443, email:

Pujita.Vaidya@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected HIV to be the focus of a meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patients' perspectives on the severity of the disease and the available therapies for the condition. Patient-Focused Drug Development is being conducted to fulfill FDA performance commitments made as part of the authorization of PDUFA under Title I of the Food and Drug Safety and Innovation

Act (FDASIA) (Public Law 112–144). The full set of performance commitments is available on the FDA Web site at

<http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf>.

FDA has committed to obtain the patient perspective in 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient community, and other interested stakeholders.

In the Federal Register of April 11, 2013 (78 FR 21613), FDA published a document that announced the disease areas for meetings in fiscal years (FY) 2013 to 2015, the first 3 years of the 5-year PDUFA V timeframe. The Agency used several criteria to develop the list of disease areas, outlined in the April 11, 2013, Federal Register document. Public comment on the Agency's proposed criteria and potential disease areas was gathered through a Federal Register document for public comment that was published on September 24, 2012 (77 FR 58849), and a public meeting that was convened on October 25, 2012. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. By the end of FY 2015, FDA will initiate another public process for determining the disease areas for FY 2016 to 2017. More information, including the list of disease areas and a general schedule of meetings, is posted on FDA's Web site at

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm>.

II. Public Meeting Information

A. Purpose and Scope of the Meeting

As part of Patient-Focused Drug Development, FDA will gather input from HIV patients and patient advocates on current approaches to managing HIV and on symptoms experienced because of HIV or its treatment. FDA is also interested in understanding patients' perspective on issues related to HIV cure research. For the purposes of this meeting, FDA considers HIV cure research to be any investigation that evaluates a therapeutic intervention intended to control or eliminate HIV infection to the point that no further medical interventions are needed to maintain health. HIV cure research is in early stages of testing in patients, but the products being evaluated may represent important approaches to treating HIV. As in many areas of research, clinical trials studying HIV cure interventions may not provide direct benefit to a participant but may provide scientific information that could guide future research and drug development. Understanding patients' perspectives on the potential benefits and risks of participating in HIV cure research studies will help FDA evaluate sponsors' study protocols and informed consent procedures.

For each of these topics, a brief initial patient panel discussion will begin the dialogue and will be followed by a facilitated discussion inviting comments from other patient and patient advocates. The draft questions for both meeting topics are as follows:

Topic 1: Patients' perspective on current approaches to managing HIV and on symptoms experienced because of HIV or its treatment

1. What are you currently doing to help manage your HIV and any symptoms you experience because of your condition or other therapies? (Examples may include prescription medicines, over-the-counter products, and non-drug therapies such as diet modification.)

- 1.1 What specific symptoms do your therapies or treatments address?

1.2 How long have you been on treatment and how has your treatment regimen changed over time?

2. How well does your current treatment regimen treat any significant symptoms of your condition?

2.1 How well have these treatments worked for you as your condition has changed over time?

2.2 Are there symptoms that your current regimen does not address at all, or does not treat as well as you would like?

3. What are the most significant downsides to your current therapies or treatments, and how do they affect your daily life? (Examples of downsides could include bothersome side effects, physical change to your body because of treatment, going to the hospital for treatment, etc.)

4. Of all the symptoms that you experience because of your condition or because of your therapy or treatment, provide one to three symptoms that have the most significant impact on your life? (Examples could include diarrhea, insomnia, difficulty concentrating, etc.)

4.1 Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your condition? (Examples of activities may include sleeping through the night, daily hygiene, driving, etc.)

5. Assuming there is currently no complete cure for your condition, what specific things would you look for in an ideal therapy or treatment to manage your condition?

Topic 2: Patients' perspectives on HIV Cure Research

1. What do you believe are the benefits of participating in an HIV cure research study?
2. What would motivate you to participate or to not participate in an HIV cure research study?
3. What risks would you find unacceptable for participating in an HIV cure research study, and why? (Examples of risks that may be associated with participation in an HIV cure research study include common side effects such as nausea and fatigue, and less common but serious adverse events such as blood clots, infection, seizures and cancer.)
4. In certain HIV cure research studies, you would be asked to stop any other HIV medications that you are currently taking. How would this affect your decision whether to participate in an HIV cure research study?
5. The process of informed consent is an important way for the researchers to communicate the purpose of an HIV research study, as well as its expected benefits and potential risks, so that people can make an informed decision whether to participate in the study.
 - 5.1 How should the informed consent clearly communicate to you the purpose of an HIV cure research study, particularly when a study is designed only to provide scientific information that could guide future research and development of treatments?
 - 5.2 How should the informed consent clearly communicate to you the potential benefits of an HIV cure research study? In particular, how should the informed consent describe benefit when we do not think that participants in the study may gain any direct health benefits?

5.3 How should informed consent communicate clearly to you the potential risks of participating in an HIV cure research study? In particular, how should the informed consent describe a study if there is very limited understanding about how the medications or interventions may affect participants or what are the potential risks of those interventions or medications?

5.4 Is there any other information that you would find helpful when deciding whether to enter an HIV cure research study?

6. What else do you want FDA to know about HIV Cure Research from your perspective?

B. Attendance and/or Participation in the Meeting

If you wish to attend this meeting, visit <http://patientfocusedhiv.eventbrite.com>. Please register by June 7, 2013. Those who are unable to attend the meeting in person can register to view a live Web cast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Web cast. Your registration will also contain your complete contact information, including name, title, affiliation, address, email address, and phone number. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of disability, please contact Pujita Vaidya (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. They will also be asked to send via email to PatientFocused@fda.hhs.gov a brief summary of responses to the topic(s) questions. Panelists will be notified of their selection soon after the close of registration on June 5. FDA will try to accommodate all patients and patient advocate participants who wish to speak, either through the panel discussion or audience participation; however the duration of comments may be limited by time constraints.

More information will be posted on the meeting Web site at least 5 days before the meeting date. Interested members of the public, including those who attend the meeting in person or through the Web cast, are invited to provide electronic or written responses to any or all of the questions pertaining to Topics 1 and 2 to the Division of Dockets Management (see ADDRESSES). Comments may be submitted until July 14, 2013.

Dated: May 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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